



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Davis, *et al.*
Application No: 09/944,389
Confirmation No: 9864
Filed: September 4, 2001
Title: Assays

Examiner: Nguyen, Bao Thuy L.
Art Unit: 1641

CERTIFICATE OF FIRST CLASS MAILING

I hereby certify that this "*Information Disclosure Statement*" is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Mail Stop: RCE, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on August 31, 2006.

Katelyn Nelson

Mail Stop: RCE
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir/Madam:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicants request consideration of this Information Disclosure Statement.

PART I: Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement is being filed concurrently with a Request for Continued Examination (RCE). No fee is believed to be due in connection with this submission. The Commissioner is hereby authorized to charge any additional fee occasioned by this paper to our Deposit Account No. 06-1448.

PART II: Information Cited

The Applicants hereby make of record in the above-identified application the information listed on the attached form PTO-1449. The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicants have earlier brought to the Examiner's attention that U.S. Patent No. 6,352,862, related to the present application, has been involved in several litigation

proceedings. In addition, U.S. Patent Nos. 5,622,871, 5,602,040, 6,228,660, 6,187,598, 5,656,503 and 6,818,455 (collectively, the "May Patents"), commonly assigned with the present application, have been involved in several litigation proceedings.

Applicants wish to make of record in the present application the following documents from these proceedings:

Expert reports and supporting documentation submitted by defendant Acon during the litigation:

- Inverness Medical Switzerland GmbH and Unipath Diagnostics, Inc. v. Acon Laboratories, "Report of Randolph Wall, Ph.D., on the Validity of the Asserted Claims of the May-Davis Patents and Exhibits," United States District Court, District of Massachusetts, Case No. 02-12303 PBS.
- Inverness Medical Switzerland GmbH and Unipath Diagnostics, Inc. v. Acon Laboratories, "Report of Gary S. David on the Invalidity Issues of the Asserted Claims of the May Patents and Exhibits," United States District Court, District of Massachusetts, Case No. 02-12303 PBS.
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- Inverness Medical Switzerland GmbH and Unipath Diagnostics, Inc. v. Acon Laboratories, "Wampole Laboratories Research and Development Laboratory Notebook 1608 for Gold Sol," United States District Court, District of Massachusetts, Case No. 02-12303 PBS.
- Inverness Medical Switzerland GmbH and Unipath Diagnostics, Inc. v. Acon Laboratories, "Declaration of Margaret M. Mazzeo," United States District Court, District of Massachusetts, Case No. 02-12303 PBS.
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Expert reports submitted by plaintiff Inverness during the litigation:

- Inverness Medical Switzerland GmbH and Unipath Diagnostics, Inc. v. Acon Laboratories, "Expert Report of David F. Katz, Ph.D. on Validity Issues Concerning the May and Davis Patents and Exhibits," United States District Court, District of Massachusetts, Case No. 02-12303 PBS.
- Inverness Medical Switzerland GmbH and Unipath Diagnostics, Inc. v. Acon Laboratories, "Expert Report of Professor Eric J. Toone on Validity Issues

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Papers relating to summary judgment motions submitted by defendant Acon during the litigation:

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- Inverness Medical Switzerland GmbH and Unipath Diagnostics, Inc. v. Acon Laboratories, "Inverness's Shortened Reply Memorandum in Support of Motion for Summary Judgment of Validity of Claims 15 and 23 of the '598 Patent and Claims 1 and 23 of the '404 Patent," United States District Court, District of Massachusetts, Case No. 02-12303 PBS.
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Applicants further wish to make of record the following document from the opposition proceedings against EP 0 560 411, which is a foreign counterpart application to the present application:

- Letter of Opponent dated December 2, 2005, European Patent Office Boards of Appeal, Opposition against EP 0 560 411

Applicants further wish to make of record the following document from the opposition proceedings against EP 0 291 194 (DE 38 87 771), which is a foreign counterpart application to the present application:

- German Patent Court Judgment Served on 7.6.2005 (translation of the original German document)

Applicants make no representation that the above-identified documents provide information material to the examination of the present application.

PART III: Additional Remarks

Documents cited on the attached form PTO-1449 are enclosed unless otherwise indicated on the attached form PTO-1449. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicants make no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

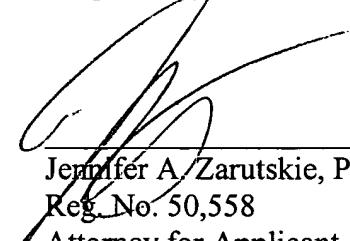
By submitting this Information Disclosure Statement, the Applicants make no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicants make no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicants, again the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

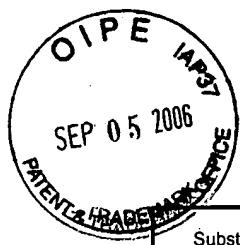
An early and favorable action is hereby requested.

Respectfully submitted,



Jennifer A. Zarutskie, Ph.D.
Reg. No. 50,558
Attorney for Applicant
Tel. No. (617) 832-1000
Fax. No. (617) 832-7000

Date: August 31, 2006
Customer No: 25181
Patent Group
Foley Hoag, LLP
155 Seaport Blvd.
Boston, MA 02210-2600



Substitute for form 1449A/B/PTO				Complete if Known	
				Application Number	09/944,389-Conf. #9864
				Filing Date	September 4, 2001
				First Named Inventor	Paul J. Davis
				Art Unit	1641
				Examiner Name	B. T. L. Nguyen
Sheet	1	of	4	Attorney Docket Number	ISA-048.06

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
A5*	US-4,727,019	02-23-1988	Valkirs et al.		
A6*	US-4,891,324	01-02-1990	Pease et al.		

FOREIGN PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
					T ⁶

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. * CITE NO.: Those application(s) which are marked with an single asterisk (*) next to the Cite No. are not supplied (under 37 CFR 1.98(a)(2)(iii)) because that application was filed after June 30, 2003 or is available in the IFW. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			T ²
	C1	Inverness Medical Switzerland GmbH and Unipath Diagnostics, Inc. v. Acon Laboratories, "Report of Randolph Wall, Ph.D., on the Validity of the Asserted Claims of the May-Davis Patents," United States District Court, District of Massachusetts, Case No. 02-12303 PBS.			
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	C5	Inverness Medical Switzerland GmbH and Unipath Diagnostics, Inc. v. Acon Laboratories, "Wampole Laboratories Research and Development Laboratory Notebook 1608 for Gold Sol," United States District Court, District of Massachusetts, Case No. 02-12303 PBS.			
	C6	Inverness Medical Switzerland GmbH and Unipath Diagnostics, Inc. v. Acon Laboratories, Inc., "Declaration of Margaret M. Mazzeo", United States District Court, District of Massachusetts, Case No. 02-12303 PBS.			
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Examiner Signature	Date Considered
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PTO/SB/08a/b (07-06)

Approved for use through 09/30/2006. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449A/B/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	09/944,389-Conf. #9864
Sheet	2	of	4	Filing Date	September 4, 2001
				First Named Inventor	Paul J. Davis
				Art Unit	1641
				Examiner Name	B. T. L. Nguyen
				Attorney Docket Number	ISA-048.06

C8	Inverness Medical Switzerland GmbH and Unipath Diagnostics, Inc. v. Acon Laboratories, "Expert Report of David F. Katz, Ph.D. on Validity Issues Concerning the May and Davis Patents and Exhibits," United States District Court, District of Massachusetts, Case No. 02-12303 PBS.	
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Examiner Signature	Date Considered
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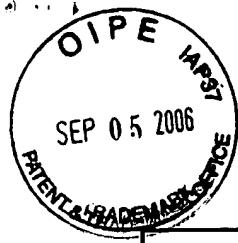
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C32	German Patent Court Judgment Served on 7.6.2005 (translation of the original German document)	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	Date Considered
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